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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,877	04/22/2002	Paul David James Blackler	P32293	6105

20462 7590 11/12/2003

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EXAMINER
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HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/12/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

10/030,877

Applicant(s)

BLACKLER ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-23 and 27-32 is/are rejected.
- 7) ☒ Claim(s) 24-26 and 33-38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 15-38 are pending.

#### ***Response to Amendment***

2. Applicant's amendment filed 10/20/03 in response to the previous Office Action (Paper No. 9) is acknowledged. Rejections of claims 1-10 and 14 under 35 U.S.C. § 112, first and second paragraph (Paper No. 9, paragraphs 5 and 7a-7d) have been obviated. The prior art rejection (Paper No. 9, item 6) has been maintained.

#### ***Allowable Subject Matter***

3. Claims 24-26 and 33-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Claim Objections***

4. Claims 16-22 are objected as being duplicates of claim 15. Claim 15 and claims 16-22 both recite the characteristics (Raman Spectrum, solid-state nuclear magnetic resonance spectrum and X-ray powder diffraction) of the polymorph, thus they are duplicates. There is only one polymorph, so all these claims must be describing the same thing.

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***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-23 and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Pool et al. (WO 94/05659). Said reference teaches the synthesis of substituted thiazolidinedione derivatives. Specifically, on page 8 (Example 2) the cited reference teaches the following salt:

5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid  
that is the same as applicants.

Claims 15-23 are product claims, in which applicants recite some of the physical and chemical characteristics of the said product. MPEP 2112 says:

“SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE  
DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).”

In this case, the “unknown property” is the particular crystalline form with X-ray diffraction pattern, with IR and Raman spectra containing peaks, and with a solid-state

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nuclear magnetic resonance spectrum containing peaks. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

"A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection."

Again, the "CHARACTERISTIC" which the prior art is silent on is the crystalline form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2<sup>nd</sup> 1241 at 1251.

Applicants are reminded that the PTO has no testing facilities. If applicants' reasoning were accepted, then any anticipation rejection of an old compound could always be overcome by tacking on some characteristic or property which the reference was silent on, regardless of whether the prior art material was any different from the claimed material. For example, if it did not happen to mention the color, one could patent an old compound just by adding "which is green" or "which is not indigo". One could put in a limitation about density (e.g. "density is not 1.4"), melting point, "refractive

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index of 2.0", solubility in some obscure solvent, spectroscopic data, and then simply point to the silence of the reference, as applicants have done here. Or one could add properties like or "does not explode on tapping" or "in the form of microneedles" or, as here, "crystals have characteristic diffraction peaks in the X-ray diffraction pattern."

In regard to claims 27-32, the pharmaceutical composition in the form of a water solution of a polymorph (compound in claim 15) and water is the same as a pharmaceutical composition in the form of water solution of a different form of the salt. Once dissolved in a solvent, the pharmaceutical composition is the same regardless of the original crystalline form.

### ***Response to arguments***

Applicants' arguments filed 10/20/2003 have been fully considered but they are not persuasive.

Applicants argue by citing a case law that reads: "[a]nticipation requires the presence in a single prior art reference disclosure of every element of the claimed invention." *Great Northern Corporation v. Davis & Pad. Co., Inc.*, 228 USPQ 356, 358 (Fed. Cir. 1986). Applicants also argue that the present invention is unique and the properties and structure of the polymorph recited in deleted claim 1, were neither described nor predicted in Pool. The examiner disagrees with applicants. Pool's compound is the same as applicants, even though the reference is silent on the properties of the compound. Please see above for details.

Applicants assert that the instant application provides methods to convert the polymorph of the present invention into polymorph described by Pool. The examiner disagrees with applicants because applicants did not show that their polymorph is different than that of Pool's. As far as we know, Pool's polymorph is the same as the claimed polymorph. It is up to applicants to show that their polymorph is different from that of Pool's by comparing the polymorphs. Applicants did not show that their starting material is different than Pool's final product or alternatively applicants did not show that their final product is the same as Pool's final product. The data to distinguish applicant's starting material from Pool's polymorph is not present in the specification.

In regard to the arguments about obviousness (*In Bristol-Myers Co. v. U.S. International Trade Commission*, 15 USPQ 2d 1258) on page 11, the issue is irrelevant since this is not an obviousness or non-obviousness issue. There is no new chemical structure because the compound is old. In regard to Applicant's argument "Pool fails to describe or suggest not only the form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleate that provides the IR, Raman, NMR and or XRPD spectral peaks., but Pool also fails to describe or suggest any process by which claimed maleate could be prepared" is not persuasive. First of all, there is no indication or proof that Pool's compound has different spectroscopic data. Secondly, the 102(b) rejection is drawn to the compounds and not to the process, thus, the argument Pool fails to describe or suggest any process by which the polymorph is formed is irrelevant. Since Pool's compound is the same as applicants, a 102(b) rejection is proper.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

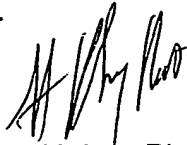
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
November 7, 2003